

Application Number 10/698,131
Amendment in Response to Office Action mailed December 27, 2007

REMARKS

This Amendment is responsive to the Office Action dated December 27, 2007. Applicant has amended claims 1, 6, 10, 16, 20 and 21, canceled claims 17-19 and 22-25, and added new claims 26-32. Claims 1-16, 20, 21, and 26-32 are pending.

Preliminary Matter

As a preliminary matter, Applicant notes that the Office Action did not address claims 20-25, which were submitted as new claims in Applicant's previous Amendment filed December 10, 2007. In this Amendment, among those new claims, Applicant has canceled claims 22-25. However, claims 20 and 21 are still pending. Because the Office Action did not address claims 20 and 21, the Office Action did not establish a prima facie case of unpatentability with respect to those claims.

Claims 20 and 21 further define the invention defined by claim 16, and specify that the bulking prosthesis comprises a first bulking prosthesis and a second bulking prosthesis, each of the first and second bulking prostheses comprising the partial cylinder shape with the substantially C-shaped cross section, and wherein implanting comprises implanting the first and second bulking prostheses proximate to the external urethral sphincter on opposite sides of the urethra of the patient.

Applicant respectfully submits that none of the applied references disclose or suggest the subject matter defined by claims 20 and 21. For example, Johnson, Goupil and Durgin fail to suggest implantation of first and second bulking prostheses having partial cylinder shapes with substantially C-shaped cross sections proximate to an external sphincter on opposite sides of the urethra of a patient. Nor did the Office Action identify any other reference that would have suggested such features.

Applicant respectfully requests that the next Office Action address claims 20 and 21. Applicant notes that new claims 26, 28, and 30 are dependent on claims 1, 6, and 10, respectively, and recite limitations similar to those set forth in claim 20.

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Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 1-13 and 15-19 under 35 U.S.C. 103(a) as being unpatentable over Johnson (US 6,338,345) in view of Goupil (US 6,652,883). The Office Action also rejected claim 14 under 35 U.S.C. 103(a) as being unpatentable over Johnson and Goupil in view of Durgin (US 6,591,838).

Applicant respectfully traverses the rejections, at least to the extent such rejections may be considered applicable to the claims as amended. The applied references fail to disclose or suggest the inventions defined by Applicant's amended claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claims 1-5

Independent claim 1, as amended, defines a method for treating urinary incontinence comprising applying vacuum pressure to an instrument proximate to a urethral wall of a patient to draw a portion of the urethral wall into a cavity in the instrument, forming a hole in the portion of the urethral wall disposed in the cavity, and implanting a bulking prosthesis through the hole proximate to a urethral sphincter. Per claim 1, the bulking prosthesis has a partial cylinder shape with a substantially C-shaped cross section and an inner surface radius that is sized to conform to close a urethra of the patient when the patient exercises voluntary control over an external urethral sphincter of the patient.

Applicant maintains that the rejection advanced in the Final Office Action is improper for substantially the same reasons stated in the Amendment filed December 10, 2007. Applicant has amended the claims, however, to expedite prosecution toward immediate allowance, without prejudice to the submission of additional claims in a continuing application. As noted above, claims 1-5 now specify that the bulking prosthesis has a partial cylinder shape with a substantially C-shaped cross section and an inner surface radius that is sized to conform to close a urethra of the patient when the patient exercises voluntary control over an external urethral sphincter of the patient.

The Office Action cited Johnson as disclosing a device used to deliver a bulking prosthesis to the body. The Office Action acknowledged that Johnson describes the device for treating GERD, and fails to teach using the bulking prosthesis for treating urinary incontinence.

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The Office Action pointed to Goupil, however, as teaching that it is well known to use a bulking material to treat a variety of problems including GERD and urinary incontinence. On this basis, the Office Action stated that modifying Johnson such that the bulking device is used to treat urinary incontinence would have been obvious in view of the Goupil device.

Applicant continues to disagree with the obviousness rejection. Again, there would have been no apparent reason for one of ordinary skill in the art to modify Johnson to conform to the claimed invention. Johnson describes a particular delivery device and technique for controllably delivering a prosthetic bulking device to treat GERD. Goupil teaches a variety of compositions for tissue bulking and coating. However, there is no teaching in Goupil that would have suggested reducing the size of the Johnson device and adapting the device for application to urinary sphincter bulking. Goupil focuses on particular compositions for bulking articles, and describes no delivery devices or techniques similar to those of Johnson for urethral bulking.

Neither Goupil nor Johnson provides any teaching that would have suggested the application of vacuum pressure to an instrument proximate to a urethral wall to draw a portion of the urethral wall into a cavity in the instrument, as set forth in claim 1. Although vacuum pressure is described by Johnson in the context of esophageal bulking for GERD, neither Johnson nor Goupil contemplates the substantial miniaturization that would have been required to render such a device suitable for use in the much smaller lumen afforded by the urethra. Nor do Johnson and Goupil provide any teaching that would have suggested a reasonable expectation of success for application of vacuum pressure to deliver bulking materials in the urethra.

The Office Action stated that "Goupil discloses that it is well known to use a bulking material to treat both GERD and urinary incontinence." In Goupil, there is no suggestion of the desirability or suitability of applying vacuum pressure to a urethral wall to deliver a bulking material. Also, as acknowledged by the Office Action, Johnson does not contemplate bulking of the urethral wall. Therefore, one of ordinary skill in the art would have found no teaching in Johnson and Goupil that would have suggested modification of the technique described by Johnson to deliver bulking prostheses proximate to the urethral sphincter, as claimed. The desirability of such a modification would have been apparent only upon access to Applicant's disclosure, which is impermissible.

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In Johnson and Goupil, there is no teaching that would have suggested adaptation of the particular delivery technique described by Johnson for esophageal bulking to support urethral bulking, notwithstanding the statement that bulking can be used for GERD or urinary incontinence. In other words, even if bulking was generally desirable for GERD and urinary incontinence, one of ordinary skill in the art still would not have appreciated the desirability of modifying and adapting the specific technique described by Johnson for esophageal bulking so that it could be used for urethral bulking, particularly given substantial differences in tissue sizes and characteristics.

Notwithstanding the arguments above, amended claim 1 further requires that the bulking prosthesis has a partial cylinder shape with a substantially C-shaped cross section and an inner surface radius that is sized to conform to close a urethra of the patient when the patient exercises voluntary control over an external urethral sphincter of the patient. Johnson and Goupil provide no teaching that would have suggested implantation of a bulking prosthesis having such features.

With respect to the limitations previously set forth in claim 10, the Office Action acknowledged that Johnson does not disclose a bulking prosthesis having a partial cylinder shape and an inner radius sized to conform to a urethra of a patient. However, the Office Action stated that Johnson teaches "a wide variety of shapes and sizes that are determined by routine experimentation and are not limited to those specifically listed." Teaching a wide variety of shapes without limitation is not equivalent to teaching the particular shape and characteristics required by Applicant's claims.

The Office Action further stated that "[s]ince it is known to use a variety of shapes this is considered to include a partial cylinder depending on the particular shape that is best for the intended use of the device." Again, Applicant disagrees with this rationale. Even if a variety of shapes could be used, there is no teaching that would have suggested the particular shape required by claim 1. Moreover, it is unclear whether the rejection is based on an assertion that such a shape is included among those described by Johnson, or would have been obvious in view of the shapes described by Johnson. It is clear that Johnson does not disclose a partial cylinder shape, much less a partial cylinder shape with a substantially C-shaped cross section, as set forth in amended claim 1.

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The Office Action again stated that Johnson teaches that the bulking prosthesis can take on a wide variety of shapes and sizes and that these optimal dimensions are patient specific and can be determined through routine experimentation of one skilled in the art. Yet, the Office Action did not identify any teaching within Johnson that would have suggested the use of a bulking prosthesis in the shape of a partial cylinder. Hence, a partial cylinder shape is not among the "wide variety of shapes and sizes" contemplated by Johnson. Goupil provides no teaching sufficient to overcome this deficiency in Johnson.

Whether it contemplates a variety of shapes or not, the Johnson reference provides no teaching concerning the specific shape required by the claims. Nor does Johnson mention how a partial cylinder or other shape would have been desirable for a particular intended use, particularly inasmuch as Johnson does not even contemplate any use within the urethra. Moreover, Johnson makes no mention of a partial cylinder shape with a substantially C-shaped cross section.

The Johnson reference, taken alone or in combination with Goupil, provides no apparent reason why one of ordinary skill in the art would select a partial cylinder shape with a substantially C-shaped cross section for a bulking prosthesis. Clearly, one of ordinary skill in the art would not have found any suggestion in Johnson or Goupil of a partial cylinder bulking prosthesis a substantially C-shaped cross section and having an inner radius that is sized to conform to close the urethra when the patient exercises voluntary control over an external urethral sphincter. These shape and dimension limitations in the claims are structural requirements and not a matter of mere intended use.

Johnson describes an esophageal bulking device 16 comprising "an oblong, cylindrical, elliptical, toric or pillow shape."¹ In addition, FIGS. 3, 4, 5 and 6 (reproduced below) of Johnson show bulking devices with generally circular or oval cross-sectional configurations. However, Johnson does not contemplate any bulking prosthesis in the shape of a partial cylinder having a substantially C-shaped cross section and an inner radius, as defined in claim 1. Johnson also fails to provide any suggestion of a similar shape or a device configured to deploy such a bulking prosthesis.

¹ Johnson et al., Col. 6, ll. 50-52.

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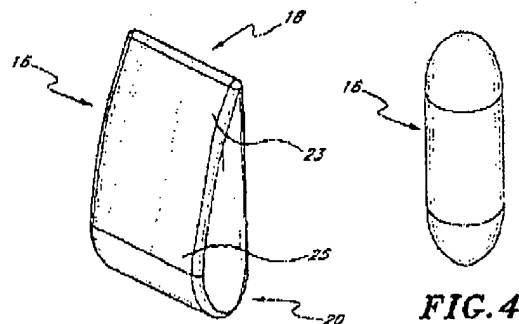


FIG. 3

FIG. 4

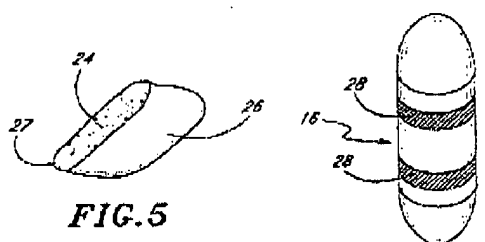


FIG. 5

FIG. 6

In addition to lacking a suggestion of a partial cylinder shape, Johnson does not teach or suggest a bulking prosthesis having an inner radius of such a partial cylinder that is sized to conform to close the urethra of a patient. Johnson describes bulking devices in which "a larger transverse cross-sectional area will produce a higher closing pressure."² Given Johnson's focus on GERD, there would have been no reason for one of ordinary skill in the art to consider a bulking prosthesis having an inner radius of the partial cylinder that is sized to conform to close the urethra of a patient. Goupil adds nothing concerning the desirability of such a shape.

FIGS. 11 and 12 of Applicant's disclosure are reproduced below and illustrate examples of bulking prostheses having partial cylinder shapes with substantially C-shaped cross sections. Johnson provides no teaching of structure similar to the structure shown in FIGS. 11 and 12.

² Johnson et al., Col. 6, ll. 45-47.

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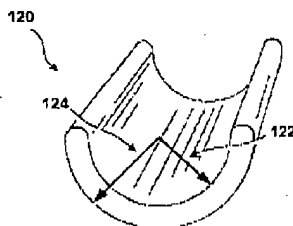


FIG. 11

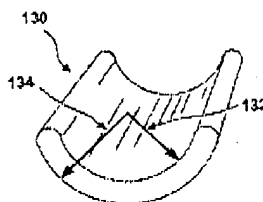


FIG. 12

The Office Action stated that Johnson discloses a toric shape, "which is defined as a convex [sic] semicircular cross section which appear to be a 'partial cylinder' shape or generally a 'C' shape." Applicant respectfully disagrees with the assertion that a toric shape, as mentioned in Johnson, would correspond to a partial cylinder shape having a substantially C-shaped cross section, as set forth in amended claim 1.

In contrast to the requirements of amended claim 1, a torus is defined by a doughnut-like ring shape that is formed by revolving a circle about an axis coplanar with the circle that does not intersect the circle.³ Such a structure does not have a partial cylinder shape or a substantially C-shaped cross section. Therefore, there is no suggestion in Johnson of a bulking prosthesis having a partial cylinder shape and a substantially C-shaped cross section, whether by the mention of a toric shape or otherwise.

Dependent claims 2-5 are allowable for at least the reasons set forth above with respect to independent claim 1, from which they depend.

For at least these reasons, the Office Action has failed to establish a prima facie case for unpatentability of Applicant's claims 1-5 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

³ www.m-w.com.

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Claims 6-9

Independent claim 6, as amended, recites a system that includes a tubular instrument sized for introduction into a urethra, the distal end including a cavity. Claim 6 also requires a vacuum port to draw a portion of a urethral wall into the cavity, a needle to make a hole through the urethral wall in the portion of the urethral wall disposed in the cavity, and a pushing agent to push a bulking prosthesis through the tubular instrument and through the hole in the urethral wall. In addition, claim 6 specifies that the bulking prosthesis has a partial cylinder shape with a substantially C-shaped cross-section and an inner surface radius sized to conform to close the urethra when the patient exercises voluntary control over an external urethral sphincter of the patient. Johnson in view of Goupil fails to teach or suggest the elements of independent claim 6, as amended.

As discussed in the previous Amendment, neither Johnson nor Goupil provides any teaching that would have suggested miniaturization of the Johnson device to include a tubular instrument sized for introduction into a urethra, as claimed. Johnson discloses a delivery device that delivers a "bulking device below a tissue surface such as below the mucosa to treat gastroesophageal reflux disease."⁴ As mentioned in the previous response, Johnson teaches that cap 50 of FIG. 16 has "an outside diameter of about 0.6 inches"⁵ and that the "outside diameter of the overtube [of FIG. 17] is about 0.7 inches."⁶ The dimensions of the Johnson device are far too large to be introduced into a urethra, and Johnson does not describe the use of the device within a urethra.

Johnson does not describe the delivery of bulking devices anywhere other than in the esophagus of a patient. In addition, there is no suggestion of modifying the scale of the Johnson device in order to allow the Johnson device to be introduced into a urethra. Goupil merely recognizes that bulking may be useful for GERD or urinary incontinence. The Goupil reference provides no suggestion of the adaptation and substantial miniaturization of the particular device described by Johnson for use in the urethra.

In addition, as discussed with reference to amended claim 1, Johnson and Goupil provide no teaching that would have suggested a bulking prosthesis having a partial cylinder shape with a

⁴ Johnson et al., Abstract.

⁵ Johnson et al., Col. 11, ll. 62-63.

⁶ Johnson et al., Col. 13, ll. 60-61.

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substantially C-shaped cross-section and an inner surface radius, wherein the inner surface radius is sized to conform to close the urethra when the patient exercises voluntary control over an external urethral sphincter of the patient. Hence, in relation to the configuration of the bulking prosthesis, amended claim 6 is patentable over Johnson and Goupil for reasons similar to those stated with reference to amended claim 1.

Dependent claims 7-9 are allowable for at least the reasons put forth with respect to independent claim 6, from which they depend. Johnson in view of Goupil fails to disclose each and every limitation set forth in claims 6-9, as amended. For at least these reasons, the cited references would not support a prima facie case of unpatentability of Applicant's claims 6-9 under 35 U.S.C. 103. Withdrawal of this rejection is requested.

Claims 10-13 and 15

Independent claim 10, as amended, defines a device comprising a bulking prosthesis in the shape of a partial cylinder having an inner radius, wherein the bulking prosthesis comprises a hydrophilic polymer that forms a hydrogel in the presence of water. Claim 10 also requires that the inner surface radius of the partial cylinder is sized to conform to close the urethra of a patient when the bulking prosthesis is implanted in the patient with an inner surface coaxial with the urethra of the patient and when the patient exercises voluntary control over an external urethral sphincter. As amended, claim 10 further specifies that the bulking prosthesis has a substantially C-shaped cross-section. Johnson and Goupil fails to teach or suggest the elements of independent claim 10, as amended.

Claim 10 is allowable for reasons similar to those described above with respect to the bulking prosthesis having a partial cylinder shape with a substantially C-shaped cross section in amended claim 1. Again, Johnson provides no teaching concerning a bulking prosthesis having a partial cylinder shape with a substantially C-shaped cross section, nor a bulking prosthesis with an inner surface radius sized to conform to close a urethra of a patient coaxial with the urethra of the patient and when a patient exercises voluntary control over an external urethral sphincter.

Dependent claims 11-13 and 15 are allowable for at least the reasons set forth with respect to independent claim 10, from which they depend.

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Johnson fails to disclose each and every limitation set forth in claims 10-13 and 15. For at least these reasons, Johnson does not support a prima facie case of unpatentability of Applicant's claims 10-13 and 15 under 35 U.S.C. 103. Withdrawal of this rejection is requested.

Claims 16-19

Independent claim 16, as amended, requires a method for treating urinary incontinence comprising applying vacuum pressure to tissue proximate the urethral sphincter, and implanting a bulking prosthesis in the portion of the tissue proximate to the urethral sphincter. The bulking prosthesis is in a miniature state at the time of implantation and assumes an enlarged state after implantation, and the bulking prosthesis includes a long dimension of at least two millimeters in the enlarged state. Amended claim 16 further specifies that the bulking prosthesis has a partial cylinder shape with a substantially C-shaped cross section and an inner surface radius that is sized to close a urethra of the patient when the patient exercises voluntary control over an external urethral sphincter of the patient.

For substantially the reasons stated above with respect to claim 1-5, it would not have been obvious to modify the delivery techniques described by Johnson to implant a bulking prosthesis in tissue proximate a urethral sphincter to treat urinary incontinence. Again, there would have been no apparent reason, whether discerned from Johnson, Goupil, or any other reference, to modify a device designed for use in the esophagus to deliver bulking agents for bulking of the urethral sphincter. Moreover, the applied references would not have suggested the use of a bulking prosthesis having a partial cylinder shape with a substantially C-shaped cross section and an inner surface radius that is sized to close a urethra of the patient when the patient exercises voluntary control over an external urethral sphincter of the patient, as claimed.

Dependent claims 20 and 21 are allowable for at least the reasons put forth with respect to independent claim 16, from which they depend. For at least these reasons, the prior art references fail to support a prima facie case for unpatentability of Applicant's claims 16, 20, and 21 under 35 U.S.C. 103(a). Withdrawal of this rejection is requested.

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Claim 14

Dependent claim 14 is allowable for at least the reasons put forth with respect to independent claim 10, from which it depends. Durgin provides no teaching sufficient to overcome the basic deficiencies evident in the Johnson reference.

New Claims:

Applicant has added new claims 26-32. Claims 26, 28, and 30 specify that a bulking prosthesis comprises first and second bulking prostheses, each comprising the partial cylinder shape with the substantially C-shaped cross section, the first and second bulking prostheses being implanted or implantable proximate to a external urethral sphincter on opposite sides of the urethra of the patient. Claims 27, 29, 31 and 32 specify that the partial cylinder shape is substantially a half cylinder shape. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. No new matter has been added by the new claims.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

3-25-08

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